

**REMARKS**

Claims 39-42, 44, 45, 47, 48, 57, 160-162 & 169-182 were pending. Herein, Applicants have amended claims 39, 40, 160, and 178 and added new claims 183-186. Accordingly, claims 39-42, 44, 45, 47, 48, 57, 160-162 & 169-186 are pending and being examined.

Support for amended claims 39, 40, 160, and 178 and new claims 183-186 may be found in the claims and specification as originally filed. Accordingly, these changes do not involve new matter and Applicants respectfully request entry of these changes.

Support for amended claim 39 may be found in the specification as originally filed at page 3, lines 12-23, page 4, lines 28-30; page 7, lines 10-36; page 18, lines 1-10 and originally filed claims 3, 16 and 40.

Support for amended claim 40 may be found in the specification as originally filed at page 3, lines 12-23 and originally filed claim 40.

Support for amended claim 160 may be found in the specification as originally filed at page 3, lines 12-23, page 4, lines 28-30; page 7, lines 10-36; page 18, lines 1-10 and originally filed claims 3, 16 and 40.

Support for amended claims 178 may be found in the specification as originally filed at page 1, lines 30-34; page 2, lines 12-32; page 12, lines 35-37; page 13, lines 1-25 and originally filed claim 17.

Support for new claims 183-184 may be found in the specification as originally filed at page 4, lines 28-30; page 7, lines 13-15 and page 18, lines 1-13.

Support for new claim 185 may be found in the specification as originally filed at page 2, lines 17-21; page 7, line 14; and page 20, lines 9-11 and lines 19-23.

Support for new claim 186 may be found in the specification as originally filed at page 4, lines 35-37; page 5, lines 1-7; and page 20, lines 9-11.

Entry of these amendments and the foregoing remarks in the file of the above-captioned patent application is respectfully requested.

In accordance with the changes to the claims and the remarks that follow, Applicant respectfully requests reconsideration of the outstanding rejections.

#### **REQUEST FOR CONTINUED EXAMINATION**

At page 2 of the Office Action, the Office states that claims 39-42, 44, 45, 47, 48, 57, 160-162 and 169-182 are pending. Further, Applicants' submission of a Request for Continued Examination on December 27, 2007 has been entered. Finally, the Information Disclosure Statement submitted by the Applicants on November 30, 2007 and December 27, 2007 have been considered by the Office. No response is due.

#### **MAINTAINED GROUNDS OF REJECTION**

##### **REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH**

At pages 2-3 of the Office Action, the Office has rejected claims 39-42, 44, 45, 47, 48, 57, 160-162 and 169-182 under 35 U.S.C. §112, first paragraph, alleging that the specification fails to comply with the written description requirement and stating that a structural and functional relationship for all of the characteristics of a clonally isolated

adipose derived stem cell that allow it to function as a stem cell that can develop into any mesodermal tissue is still not provided.

Applicants respectfully disagree.

The specification defines the distinguishing characteristics of a stem cell derived from adipose tissue. For example, at page 4, line 28, Applicants disclose that expression of telomerase can serve as a stem-cell marker. Further, at page 7, lines 13-15, Applicants disclose that one measurement of differentiation of adipose derived stem cells is the telomere length, undifferentiated stem cells having longer telomeres than differentiated cells; the cells can be assayed for the level of telomerase activity. Additionally, at page 18, lines 1-13 of the specification as originally filed, Applicants show that when the adipose derived stem cells were assayed for telomerase using the commercially available TRAP assay kit, telomeric ladders representing telomerase activity were observed. Thus, the adipose-derived stem cells express telomerase activity similar to that previously reported for human stem cells.

The claimed invention is directed towards a method of differentiating clonally isolated stem cells having telomeric activity obtained from adipose tissue wherein the stem cells differentiate into cells of any two or more of a fat cell, a bone cell, a cartilage cell, and a muscle cell comprising culturing the stem cell in any of adipogenic, osteogenic, chondrogenic, and myogenic morphogenic medium under conditions sufficient for the cell to differentiate. Accordingly, the specification as originally filed teaches methods for isolating adipose derived stem cells (Examples 1 and 3) and further, as discussed *supra*, teaches how to identify a stem cell, i.e. by assaying for telomerase activity, in addition to what they are required to become eventually. Applicants' disclosure provides the essential characteristics of adipose derived stem cells.

Further, Applicants have deposited adipose derived stem cells lending further support that Applicants were in possession of the invention.

Accordingly, in view of the arguments above, Applicants respectfully request that the Office withdraw the rejection.

**REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH**

At pages 3-4 of the Office Action, the Office has rejected claims 39-42, 44, 45, 47, 48, 57, 160-162 and 169-182 under 35 U.S.C. §112, second paragraph, alleging that the metes and bounds of the term “derived” is unclear.

Applicants respectfully disagree.

However, in the interest of furthering prosecution of the subject application, Applicants have amended the instant claims to recite “isolated stem cell ... obtained from adipose tissue”.

For the record, Applicants point out that there is ample support for the recitation of “adipose-derived stem cell” in the specification as originally filed. For instance, support for the recitation of “adipose-derived stem cell” and how such cells are obtained, may be found in the specification as originally filed at page 2, lines 5-7; page 8, lines 8-13; Example 1; Example 3; and Abstract.

**WITHDRAWN REJECTIONS**

At pages 4-5 of the Office Action, the Office states that the following rejections have been withdrawn:

- (i) rejection of claims 39, 40, 41, 45, 57 and 160 under 35 U.S.C. §102(e) as being anticipated by Halvorsen et al. (US 2002/0119126);
- (ii) rejection of claim 161 under 35 U.S.C. §103(a) as being anticipated by Halvorsen et al. (US 2002/0119126) in view of Golde et al. (US Patent No. 4,438,032);
- (iii) rejection of claim 162 under 35 U.S.C. §103(a) as being anticipated by Halvorsen et al. (US 2002/0119126) in view of Gimble et al. (US Patent No. 6,555,374); and
- (iv) provisional rejection of claims 39-42, 44, 45, 48, 67 and 160 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 58-60, 67, 76-78, 80, 81, 83 and 84 of copending Application No. 10/845,315.

#### **NEW GROUNDS OF REJECTION**

#### **CLAIM OBJECTION**

At page 5 of the Office Action, the Office has objected to claim 40 as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicants' claim amendment renders the objection moot. Applicants respectfully request that the Office withdraw the objection.

#### **REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH**

At page 6 of the Office Action, the Office has rejected claims 40 and 178 under 35 U.S.C. §112, second paragraph as follows:

- (i) The Office alleges that that the metes and bounds of claim 40 are unclear.

Applicants have amended claim 40 to delete recitation of the terms “cardiogenic”, “dermatogenic”, “embryonic”, “fetal” and “stromogenic”. Accordingly, Applicants’ claim amendment renders the objection moot. Applicants respectfully request that the Office withdraw the objection.

- (ii) The Office alleges that recitation of “such as” in claim 178 renders the claim indefinite.

Applicants have amended claim 178 to recite “wherein the extracellular matrix materials comprise” instead of “such as”. Accordingly, Applicants claim amendment renders the rejection moot. Applicants respectfully request that the Office withdraw the rejection.

**CONCLUSION**

If a telephone interview would be of assistance in advancing the prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone her at the number provided below.

No fees, other than fees for one-month extension of time (\$60.00), are deemed necessary in connection with the filing of this Amendment. If any further fee is necessary, the Patent Office is authorized to charge any additional fee to Deposit Account No. 50-0306.

Respectfully submitted,



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